Complete Summary

GUIDELINE TITLE

Revised recommendations for HIV screening of pregnant women.

BIBLIOGRAPHIC SOURCE(S)

Revised recommendations for HIV screening of pregnant women. MMWR Recomm Rep 2001 Nov 9;50(RR-19):59-86. [87 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

GUIDELINE CATEGORY

Counseling
Prevention
Screening

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To revise the 1995 Public Health Service guidelines for human immunodeficiency virus (HIV) counseling and testing in pregnant women (MMWR 1995;44[No. RR-7]:1-14).
- To provide guidance to public- and private-sector policy makers and clinical providers on HIV screening during pregnancy
- To reduce barriers to voluntary HIV testing for all pregnant women in the United States and to make the voluntary counseling and testing process simple and routine in prenatal settings

TARGET POPULATION

- All pregnant women in the United States
- Infants with perinatal exposure to human immunodeficiency virus (HIV)

INTERVENTIONS AND PRACTICES CONSIDERED

Screening for HIV in Pregnant Women and Their Infants

1. Universal testing of pregnant women for HIV infection as early as possible during pregnancy (prevention of perinatally-acquired HIV)
2. Universal retesting in the third trimester
3. Testing at labor and delivery for women who have not received prenatal testing and chemoprophylaxis

Education and Prevention Counseling of Pregnant Women Regarding HIV

1. Provision of information regarding HIV and assessment of risks for HIV infection
2. Referral of high-risk women to HIV risk-reduction services

HIV Testing

1. HIV antibody testing according to the recommended algorithm, which includes enzyme immunoassay (EIA) to test for antibody to HIV and confirmatory testing with a more specific assay (e.g., Western blot)

Counseling and Follow-up of HIV-infected Pregnant Women

1. HIV prevention counseling

2. Counseling regarding antiretroviral therapy: antiretroviral chemoprophylaxis using zidovudine (ZDV)
3. Counseling to avoid breast-feeding to eliminate risk for postnatal transmission
4. Postpartum follow-up of infected women and exposed children

MAJOR OUTCOMES CONSIDERED

- Perinatal transmission of HIV-1 virus from mother to newborn
- Sensitivity and specificity of HIV testing assays
- Offering and acceptance of HIV testing in pregnant women

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The following revised recommendations for HIV screening of pregnant women are based on scientific and clinical advances in preventing perinatally acquired HIV and caring for HIV-infected women, recommendations from the Institute of Medicine (IOM), consultations with specialists in the field, and public opinion. They reflect the need for universal HIV testing of all pregnant women and simplification of the pretest process so that operational procedures do not impede women from benefiting from proven measures to prevent perinatal transmission and from other advances in the care and treatment of HIV disease. Although universal testing is recommended, testing should remain a voluntary decision by the pregnant woman.

Screening for HIV in Pregnant Women and Their Infants

- The U.S. Public Health Service (PHS) recommends that all pregnant women in the United States be tested for HIV infection. All health-care providers should recommend HIV testing to all of their pregnant patients, pointing out the substantial benefit of knowledge of HIV status for the health of women and their infants. HIV screening should be a routine part of prenatal care for all women.
- HIV testing should be voluntary and free of coercion. Informed consent before HIV testing is essential. Information regarding consent can be presented orally or in writing and should use language the client understands. Accepting or refusing testing must not have detrimental consequences to the quality of prenatal care offered. Documentation of informed consent should be in writing, preferably with the client´s signature. State or local laws and regulations governing HIV testing should be followed. HIV testing should be presented universally as part of routine services to pregnant women, and confidential informed consent should be maintained (see the related guidelines titled "Revised Guidelines for HIV Counseling, Testing, and Referral" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):1-58; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]).
- Although HIV testing is recommended, women should be allowed to refuse testing. Women should not be tested without their knowledge. Women who

refuse testing should not be coerced into testing, denied care for themselves or their infants, or threatened with loss of custody of their infants or other negative consequences. Discussing and addressing reasons for refusal (e.g., lack of awareness of risk or fear of the disease, partner violence, potential stigma, or discrimination) could promote health education and trust-building and allow some women to accept testing at a later date. Women who refuse testing because of a previous history of a negative HIV test should be informed of the importance of retesting during pregnancy. All logistical reasons for not testing (e.g., scheduling) should be addressed as well. Health-care providers should remember that some women who initially refuse testing might accept at a later date, particularly if their concerns are discussed. Some women who refuse confidential testing might be willing to obtain anonymous testing. However, they should be informed that if they choose anonymous testing, no documentation of the results will be recorded in the medical chart, and their providers might have to retest them, potentially delaying provision of antiretroviral drugs for therapy or perinatal prophylaxis. Some women will continue to refuse testing, and their decisions should be respected.

- Before HIV testing, health-care providers should provide the following minimum information. Although a face-to-face counseling session is ideal, other methods can be used (e.g., brochure, pamphlet, or video) if they are culturally and linguistically appropriate.
    - HIV is the virus that causes AIDS. HIV is spread through unprotected sexual contact and injection-drug use. Approximately 25% of HIV-infected pregnant women who are not treated during pregnancy can transmit HIV to their infants during pregnancy, during labor and delivery, or through breast-feeding.
    - A woman might be at risk for HIV infection and not know it, even if she has had only one sex partner.
    - Effective interventions (e.g., highly active combination antiretrovirals) for HIV-infected pregnant women can protect their infants from acquiring HIV and can prolong the survival and improve the health of these mothers and their children.
    - For these reasons, HIV testing is recommended for all pregnant women.
    - Services are available to help women reduce their risk for HIV and to provide medical care and other assistance to those who are infected.
    - Women who decline testing will not be denied care for themselves or their infants.
- Health-care providers should perform HIV testing in consenting women as early as possible during pregnancy to promote informed and timely therapeutic decisions. Retesting in the third trimester, preferably before 36 weeks of gestation, is recommended for women known to be at high risk for acquiring HIV (e.g., those who have a history of sexually transmitted diseases [STDs], who exchange sex for money or drugs, who have multiple sex partners during pregnancy, who use illicit drugs, who have sex partner[s] known to be HIV-positive or at high risk, and who have signs and symptoms of seroconversion). Routine universal retesting in the third trimester may be considered in health-care facilities with high HIV seroprevalence among women of childbearing age. Retesting for syphilis during the third trimester and again at delivery also is recommended for pregnant women at high risk (CDC, 1998). Some states mandate syphilis screening at delivery for all pregnant women.

- Women admitted for labor and delivery with unknown or undocumented HIV status should be assessed promptly for HIV infection to allow for timely prophylactic treatment. Expedited testing by either rapid return of results from standard testing or use of rapid testing (with confirmation by a second licensed test when available) is recommended for these women. The goal is to identify HIV-infected women or their infants as soon as possible because the efficacy of prophylactic therapy is greatest if given during or as soon after exposure as possible (i.e., within 12 hours of birth). Informed consent is essential for women tested prenatally, and women in labor with unknown status should be allowed to refuse testing without undue consequences. After delivery, standard confirmatory testing should be done for women with positive rapid test results.
- Some women might not (a) receive testing during labor and delivery, (b) choose to be tested for HIV, or (c) retain custody of their infants. If the mother has not been tested for HIV, she should be informed that knowing her infant´s infection status has benefits for the infant´s health and that HIV testing is recommended for her infant. Providers should ensure that the mother understands that a positive HIV antibody test for her infant indicates infection in herself. For infants whose HIV infection status is unknown and who are in foster care, the person legally authorized to provide consent should be informed that HIV testing is recommended for infants whose biological mothers have not been tested. Testing should be performed in accordance with the policies of the organization legally responsible for the child and with prevailing legal requirements for HIV testing of children.
- Regulations, laws, and policies regarding HIV screening of pregnant women and infants are not standardized throughout all states and U.S. territories. Health-care providers should be familiar with and adhere to state/local laws, regulations, and policies concerning HIV screening of pregnant women and infants.

Education and Prevention Counseling of Pregnant Women Regarding HIV

When the pretest process is simplified to providing essential information, the value of prevention counseling should not be lost. For some women, the prenatal care period could be an ideal opportunity for HIV prevention and subsequent behavior change to reduce risk for acquiring HIV infection. Thus, the following steps are recommended:

- Information regarding HIV and assessment of risks for HIV infection (i.e., risk screening) should be provided to all pregnant women as part of routine health education. Reluctance to provide HIV prevention counseling should never be a barrier to HIV testing. Similarly, a focus on increased HIV testing should not be a barrier to providing effective HIV prevention counseling for persons determined to be at increased risk for acquiring or transmitting HIV (see the related guidelines titled "Revised Guidelines for HIV Counseling, Testing, and Referral" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):1-58; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]).
- Pregnant women found to have behaviors that place them at high risk for acquiring HIV infection (e.g., multiple sex partners, current diagnosis or history of sexually transmitted diseases, exchange of sex for money or drugs, substance abuse) or who want more intensive client-centered HIV prevention

counseling should be provided with or referred to HIV risk-reduction services (e.g., drug treatment, sexually transmitted diseases treatment, HIV centers with personnel trained in HIV counseling).

Interpretation of HIV Test Results

- HIV antibody testing should be performed according to the recommended algorithm, which includes an enzyme immunoassays (EIA) to test for antibody to HIV and confirmatory testing with a more specific assay (e.g., Western blot). All assays should be performed according to manufacturers´ instructions and state and federal laboratory guidelines.
- HIV infection (as indicated by the presence of antibody to HIV) is defined as a repeatedly reactive enzyme immunoassay and a positive confirmatory supplemental test. Confirmation or exclusion of HIV infection in a person with indeterminate test results should be based on HIV antibody test results, consideration of the person´s medical and behavioral history, results from additional virologic and immunologic tests when performed, and clinical follow-up (see the related guidelines titled "Revised Guidelines for HIV Counseling, Testing, and Referral" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):1-58; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]). Whenever possible, uncertainties regarding HIV infection status, including laboratory test results, should be resolved before final decisions are made regarding reproductive options, antiretroviral therapy, cesarean delivery, or other interventions.
- Pregnant women who have repeatedly reactive enzyme immunoassays and indeterminate supplemental tests should be retested for HIV antibody to distinguish between recent seroconversion and a negative test result. Almost all nonpregnant HIV-infected persons with indeterminate Western Blot will develop detectable HIV antibody within 1 month of exposure to the virus; relevant data are not available for pregnant women. Although viral deoxyribonucleic acid/ribonucleic acid (DNA/RNA) assays can be helpful, they are not U.S. Food and Drug Administration (FDA)-approved for diagnostic use.
- Women who have negative enzyme immunoassays or rapid test results and those who have repeatedly reactive enzyme immunoassays but negative supplemental tests should be considered uninfected unless they have had a recent HIV exposure. A negative test result provides information regarding the woman´s status, but does not ensure that a sexual or needle-sharing partner is uninfected.
- As additional rapid assays become licensed and available in the United States, specific combinations of $\geq$2 different rapid HIV tests for diagnosis of HIV infection in women who do not receive health care until labor might be useful because combinations of rapid tests have provided results as reliable as those from the enzyme immunoassay/Western blot combination (Branson, 2000). Until other rapid assays are available, some women who are reactive on a single rapid test might consider prophylactic treatment until HIV infection is ruled out. Confirmatory standard testing should be done after delivery for women with a positive rapid test result.

Recommendations for HIV-Infected Pregnant Women

- HIV-infected pregnant women should receive HIV prevention counseling as recommended (see the related guidelines titled "Revised Guidelines for HIV Counseling, Testing, and Referral" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):1-58; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]). This counseling should include discussion of the risk for perinatal HIV transmission, ways to reduce this risk, and the prognosis for infants who become infected. HIV-infected pregnant women should also be told the clinical implications of a positive HIV antibody test result and the need for and benefit of HIV-related medical and other early intervention services, including how to access these services.
- HIV-infected pregnant women should be counseled regarding antiretroviral therapy during pregnancy to improve their health (HIV/AIDS Treatment Information Service [ATIS], 2001) and prevent perinatal transmission (HIV/ATIS, 2001). Medical care and management of HIV-infected persons, especially pregnant women, can be complicated because of the need for combination therapy with multiple drugs, management of common side effects, careful monitoring of viral load and drug resistance, prophylaxis for and treatment of opportunistic infections, and monitoring of immune status. Health-care providers who are not experienced in the care of pregnant HIV-infected women are encouraged to obtain referral for specialty care from providers who are knowledgeable in this area.

Although pregnancy is not an adequate reason to defer therapy for HIV infection, unique considerations exist regarding use of antiretroviral drugs during pregnancy, including the potential need to alter dosing because of physiologic changes associated with pregnancy, the potential for adverse short- or long-term effects on the fetus and infant, and the effectiveness in reducing the risk for perinatal transmission (HIV/AIDS Treatment Information Service [ATIS], 2001).

- Obstetric providers should adhere to best obstetric practices, including offering scheduled cesarean section at 38 weeks to reduce risk for perinatal HIV transmission (Biggar, Miotti, & Taha, 1996; American College of Obstetricians and Gynecologists, 1999).
- HIV-infected pregnant women should receive information regarding all reproductive options. Reproductive counseling should be nondirective. Healthcare providers should be aware of the complex concerns that HIV-infected women must consider when making decisions regarding their reproductive options and should be supportive of any decision.
- To eliminate the risk for postnatal transmission, HIV-infected women in the United States should not breast-feed. Support services for use of appropriate breast milk substitutes should be provided when necessary. The Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization recommendations for HIV and breast-feeding should be followed in international settings (WHO Technical Consultation on Behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-agency Task Team on Mother-to-Child Transmission of HIV, 2000).
- To optimize medical management, positive and negative HIV test results should be available to a woman´s health-care provider and included on her confidential medical records and those of her infant. After informing the mother, maternal health-care providers should notify the pediatric-care providers of the impending birth of an HIV-exposed infant and any anticipated complications. If HIV is first diagnosed in the infant, health-care providers

should discuss the implications for the mother´s health and help her obtain care. Women should also be encouraged to have their other children tested for HIV. Children can be infected with HIV for many years before complications occur. Providers are encouraged to build supportive health-care relationships that promote discussion of pertinent health information. Confidential HIV-related information should be disclosed or shared only in accordance with prevailing legal requirements.

- After receiving their test results, HIV-infected pregnant women should receive counseling, including assessment of the potential for negative effects (e.g., discrimination, domestic violence, psychological difficulties). Counseling should also include information on how to minimize these consequences, assistance in identifying supportive persons in their own social networks, and referral to appropriate psychological, social, and legal services. HIV-infected women should be counseled regarding the risk for transmission to others and ways to decrease this risk. They also should be told that discrimination based on HIV status or AIDS in housing, employment, state programs, and public accommodations (including physicians´ offices and hospitals) is illegal.
- Health-care providers should thoroughly assess the prevention service needs of HIV-infected women (e.g., substance abuse, sexually transmitted diseases treatment, partner referral, or family planning services) and develop a plan to promote access to and use of these services (see the related guidelines titled "Revised Guidelines for HIV Counseling, Testing, and Referral" [MMWR Recomm Rep 2001 Nov 9;50(RR-19):1-58; a related National Guideline Clearinghouse (NGC) Guideline Summary is also available]).
- Health-care providers should follow the U.S. Public Health Service Task Force recommendations for using antiretroviral drugs to treat pregnant HIV-1 infected women and reduce perinatal HIV-1 transmission in the United States, which address treating pregnant women who do not receive health care until near the time of delivery. These recommendations are available at the HIV/AIDS Treatment Information Service (ATIS) Web site (HIV/ATIS, 2001)

Recommendations for Postpartum Follow-Up of Infected Women and Perinatally Exposed Children

- HIV-infected women should receive ongoing HIV-related medical care, including immune-function monitoring, recommended therapy, and prophylaxis for and treatment of opportunistic infections and other HIV-related conditions (HIV/AIDS Treatment Information Service [ATIS], 2001; CDC, 1999). HIV-infected women should receive gynecologic care, including regular Pap smears, reproductive counseling, information on how to prevent sexual and drug-related transmission of HIV, and treatment of gynecologic conditions according to published recommendations (CDC, 1999). Obstetrical providers should ensure that HIV-infected women are introduced or referred to another provider to continue their care after pregnancy.
- HIV-infected women (or their children´s guardians) should be informed of the importance of follow-up for their children. Children whose HIV infection status is unknown require early diagnostic testing and prophylactic therapy to prevent Pneumocystis carinii pneumonia (PCP) pending determination of their status.
    - Infected children require follow-up care to determine the need for prophylactic therapy and antiretroviral treatment and to monitor

disorders in growth and development that often occur before age 24 months.
    - Uninfected children who are exposed to antiretroviral therapy should be assessed for potential short- and long-term side effects.
- Identification of an HIV-infected mother indicates that her family needs or will need medical and social services as her disease progresses. Thus, health-care providers should ensure that referrals to services address the needs of the entire family.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Because of recent advances in both antiretroviral and obstetrical interventions, pregnant women infected with HIV who know their status prenatally can reduce their risk for transmitting HIV to their infants to ≤2%. The guidelines may reduce barriers to voluntary HIV testing for all pregnant women in the United States and make the voluntary counseling and testing process simple and routine in prenatal settings.

Subgroups Most Likely to Benefit:

- Women who lack prenatal care
- Women who are not being offered voluntary HIV counseling and testing during pregnancy

POTENTIAL HARMS

For the individual woman, the substantial benefits of HIV testing must be weighed against the possible risks. Potential negative consequences of a diagnosis of HIV infection can include loss of confidentiality, job- or health-care--related discrimination and stigmatization, loss of relationships, domestic violence, and adverse psychological reactions. Providing HIV-infected women with or referring them to psychological, social, and legal services could help minimize these risks

and allow more women to benefit from the health advantages of early HIV diagnosis without adverse consequences.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines maintain a voluntary approach to HIV testing. This voluntary approach preserves a woman's right to make decisions regarding testing and supports a woman´s right to refuse testing if she does not think it is in her best interest.
- The guideline does not address other concerns related to continued perinatal transmission (e.g., lack of prenatal care). Centers for Disease Control and Prevention (CDC) programs targeted to states with the highest incidence of perinatal HIV infection address these ongoing public health problems (information on these programs is available from the Centers for Disease Control and Prevention Web site).
- The guideline applies only to the United States; different recommendations, especially on breast-feeding, will apply in other countries.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Revised recommendations for HIV screening of pregnant women. MMWR Recomm Rep 2001 Nov 9;50(RR-19):59-86. [87 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Nov 9

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. These guidelines replace the Centers for Disease Control and Prevention (CDC) 1995 guidelines titled "U.S. Public

Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing for Pregnant Women" (MMWR 1995;44[No. RR-7]:1-14).

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 12, 2002.

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